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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/077,154      | 02/15/2002  | Timothy J. Martins   | 27866/36007A        | 5576             |

4743 7590 03/07/2003

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1626

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DATE MAILED: 03/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

|                               |                                |
|-------------------------------|--------------------------------|
| Application No.<br>10/077,154 | Applicant(s)<br>MARTINS ET AL. |
| Examiner<br>EBENEZER SACKY    | Art Unit<br>1626               |



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Jan 27, 2003

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

4)  Claim(s) 47-50 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 47-50 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

This is a response to applicants amendment filed on 01/27/03. Claims 46-51 are pending. Applicants have canceled claims 46 and 51, accordingly, claims 47-50 are at issue.

### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly

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owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Claim Rejections - 35 U.S.C. § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Under the definition of R<sup>7</sup>, amended claim 50, page 7, line 18, applicants have defined R<sup>7</sup> as "optionally substituted with one or more of RO<sup>8</sup>." RO<sup>8</sup> appears to be a typographical error, since it is impossible to have "8" oxygen atoms attached at substituent R<sup>7</sup>. The correct definition should be OR<sup>8</sup> as defined in the specification on page 14, line 13. Correction is required.

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***Obviousness-Type Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 47-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 17 of 6,455,562 and 6,294,561(Fowler et al.); and claim 25 of U.S. Patent No 6,376,489.

Applicants claim a method of inhibiting the activation of human T-lymphocytes in a mammal comprising the administration of a phosphodiesterase compound of formula (II). Fowler et al., '562' discloses a method of inhibiting the activation of human T-lymphocytes using a phosphodiesterase compound similar to the instantly claimed compound for inhibiting the activation of human T-lymphocyte. See column 6, lines 1-51, column 12, lines 6-8 and claim 4. The instant method differs from '562' in the generic description of the compound. Note the overlap of the claimed R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>10</sup> and the corresponding R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>10</sup> of Fowler et al. The instant alkyl-amine of R<sup>4</sup>, R<sup>5</sup>, R<sup>6</sup> and R<sup>12</sup> at the 3-position of the

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pyrrolidine ring corresponds to R<sup>7</sup> of Fowler et al., wherein R<sup>7</sup> is branched or unbranched alkyl groups substituted by NR<sup>8</sup>R<sup>9</sup>, wherein R<sup>8</sup> and R<sup>9</sup> can be taken together with the nitrogen to which they are attached to form a 5-membered ring such as a tetrazole or an oxatriazole, and further, instant R<sup>7</sup> can be heteroaryl or heterocycle which corresponds to tetrazole or oxatriazole of Fowler et al.

The instant method also differs from Fowler et al., '561' in the generic description of the compound. Note the overlap of the claimed R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>10</sup> and the corresponding R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>10</sup> of Fowler et al. The instant alkyl-amine of R<sup>4</sup>, R<sup>5</sup>, R<sup>6</sup> and R<sup>12</sup> at the 3-position of the pyrrolidine ring corresponds to R<sup>7</sup> of Fowler et al., wherein R<sup>7</sup> is branched or unbranched alkyl groups substituted by NR<sup>8</sup>R<sup>9</sup>, wherein R<sup>8</sup> and R<sup>9</sup> can be taken together with the nitrogen to which they are attached to form a 5-membered ring such as a tetrazole or an oxatriazole, and furthermore, instant R<sup>7</sup> can be heteroaryl or heterocycle which corresponds to tetrazole or oxatriazole of Fowler et al. See column 6, lines 10-65. Additionally, Fowler et al., '561' differs in treating the inhibition of cAMP-specific PDE using a

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compound similar to the instantly claimed compound. However, PDE4 inhibitors are known to be useful for treating a variety of inflammatory diseases of which T-lymphocytes is inclusive. See column 12, lines 31-33 and claim 17 of '561'; and column 6, lines 10-53 and claim 25 of '489'.

Martins et al., '489', also disclose a method of treating or the inhibition of cAMP-specific PDE. See the entire patent, especially claim 25, column 60. The difference between Martins et al., and the instant method is that Martins et al., is drawn to the inhibition of cAMP-specific PDE, whereas the instant method is drawn to the inhibition of the activation of T-lymphocytes. PDE4 inhibitors are known to be useful for treating a variety of inflammatory diseases of which T-lymphocytes is inclusive. See column 12, lines 6-8 of Fowler et al., (561) and page 1, lines 27-30 of the specification. Note the overlap of R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup>, R<sup>6</sup>, R<sup>7</sup>, R<sup>10</sup> and R<sup>12</sup> of the instant compound and the compound of Fowler et al.

Accordingly, the skilled artisan would be motivated to employ the use of the structurally similar compounds of Fowler et al., and Martins et al., in

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treating disease state with the expectation of obtaining an additional method for inhibiting the activation of T-lymphocytes.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS

March 6, 2003

Joseph K. McKane

Joseph K. McKane

Supervisory Patent Examiner

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